



Memorandum

To: Kristine Koch and Chip Humphrey, EPA Region 10
From: Lower Willamette Group
CC:
Date: June 08, 2012
Re: Protectiveness Criterion for the Evaluation of Alternatives

1. INTRODUCTION

During the Lower Willamette Group's (LWG) two day draft Feasibility Study (FS) roll-out meeting with the Environmental Protection Agency (EPA) and its partners, there were a few questions raised by the EPA team about how the various alternatives were evaluated against the National Contingency Plan (NCP) protectiveness criterion. The purpose of this memorandum is to provide EPA with additional information and insight as to how the LWG evaluated the protectiveness criterion in the draft FS.

The specific observation by EPA relates to the interpretation of protectiveness and background chemical concentrations. Specifically, the comments inferred that even if alternatives achieve background concentrations for contaminants of concern, the alternatives would not be "protective" because they exceed risk-based preliminary remediation goals (PRGs) for one or more exposure scenarios. There was little discussion of the comment in the meeting, and the context of the comment was not clarified.

There appears to be a significant difference between EPA's discussion of "protectiveness" and LWG's understanding of "protectiveness" in an FS context. The NCP and EPA's policy for interpretation of protectiveness is much broader than an evaluation of whether there are exceedences of risk-based PRGs derived from the baseline risk assessments. The purpose of this memorandum is to outline that policy and precedent in the context of the evaluation that was presented in the draft FS. The LWG hopes that this information is useful to EPA during its detailed review of the draft FS.

2. DEFINITION OF PROTECTIVENESS

The NCP provides nine criteria by which alternatives in an FS are evaluated. Protectiveness is considered a threshold criterion because it must be met in order for an alternative to be eligible for selection.

The NCP defines protectiveness as:

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“(A) Overall protection of human health and the environment. Alternatives shall be assessed to determine whether they can adequately protect human health and the environment, in both the short- and long-term, from unacceptable risks posed by hazardous substances, pollutants, or contaminants present at the site by eliminating, reducing, or controlling exposures to levels established during development of remediation goals consistent with § 300.430(e)(2)(i). Overall protection of human health and the environment draws on the assessments of other evaluation criteria, especially long-term effectiveness and permanence, short-term effectiveness, and compliance with ARARs.” 40 C.F.R. 300.430(e)(9)(iii)(A) (emphasis added).

Protectiveness evaluates whether an alternative is “adequate” at protecting human health and the environment based on what is deemed to be the “unacceptable risks” at the site. The evaluation takes into account short- and long-term protectiveness, various remediation methods, and the levels set by the remedial goals. The determination of what is “adequate” protection of an “unacceptable risk” occurs at the risk management stage, and is explained further in the NCP and the Preamble to the final NCP rule.

First, the risk assessment is “one factor in the determination of what is protective.” 55 Fed. Reg. 8714 (1990). Risk characterization in the baseline risk assessments present the risks and the associated uncertainties. 55 Fed. Reg. 8711 (“The results of the risk assessment are used to understand the types of exposures and risks that may result from Superfund Sites”). EPA guidance on risk assessments relies on a concept of reasonable maximum exposure, which is designed to include all “exposures that can be reasonably expected to occur, but does not focus on worst-case exposure assumptions.” 40 C.F.R. 300.430(d). EPA Guidance further recognizes that “[o]verly conservative assumptions, when combined, can lead to unrealistic estimates of risk.” (Guidelines for Carcinogen Risk Assessment. EPA/630/P-03/001F. March 2005.) In addition, the “Risk Characterization should include a discussion of elevated background concentrations of COPCs and their contribution to site risks,” as well as their associated uncertainties. (Role of Background in the CERCLA Cleanup Program. OSWER 9285.6-07P. April 26, 2002; 55 Fed. Reg. 8710.)¹ All of these assumptions and uncertainties are presented as part of the risk characterization for consideration in risk management.

However, the risk assessment is not the only factor that EPA considers. The assessment of protection also draws on other evaluation criteria, especially long-term effectiveness and short-term effectiveness. 40 C.F.R. 300.430(e)(9)(iii)(A); 55 Fed. Reg. 8720. Long-term effectiveness, in turn, considers the residual risk remaining at a site after the remedial action is complete and notes that the “assessment of risk is conducted assuming conservative but realistic exposures.” 55 Fed. Reg. 8720.

Additionally, determining acceptable risk is influenced by the balancing of criteria to identify site-specific trade-offs between options. These trade-offs are balanced in a risk management judgment as to which alternative provides the most appropriate solution for the

¹ Additional references related to risk characterization and the role of background is included in Attachment A.

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site problem, and the balancing of criteria help define the appropriate (or acceptable) risk level. As EPA states in the Preamble to the NCP:

“[T]he use of preliminary remediation goals does not preclude the development and consideration or selection of alternatives that attain other risk levels. Final selection of the appropriate level of risk is made based on the balancing of criteria in the remedy selection step of the process.” 55 Fed. Reg. 8713.

This concept is described more specifically under Section 300.430(e)(2)(i) of the NCP in the context of setting final remedial goals. As stated above, “protectiveness” is ultimately defined by the final remedial goal. Remedial goals are established based on “acceptable exposure levels that are protective of human health and the environment” considering several factors including ARARs, acceptable exposure levels for carcinogens, factors related to technical limitations, “factors related to uncertainty,” and “other pertinent information.” 40 C.F.R. 300.430(e)(2)(i). The uncertainty factors to be considered in setting the remedial goals include an evaluation of the risk assessment and “whether the risks are likely to have been under- or overestimated.” 55 Fed. Reg. 8711. While the risk assessment and ARARs may guide the preliminary remediation goals, as more information is learned during the RI/FS, the preliminary remedial goals are modified. Final remediation goals are not set until the Record of Decision. 40 C.F.R. 300.430(e)(2)(i). In any event, remediation goals are not set below background concentrations. Role of Background in the CERCLA Cleanup Program. OSWER 9285.6-07P. April 26, 2002 (“Generally, under CERCLA, cleanup levels are not set at concentrations below natural background levels. Similarly, for anthropogenic contaminant concentrations, the CERCLA program normally does not set cleanup levels below anthropogenic background concentrations.”)

Finally, the NCP definition of protectiveness includes the ability to achieve the protective levels through various remedial technologies that eliminate, reduce or control exposures. As explained in the Preamble to the Final NCP, when treatment of contaminants is impracticable, “remedies that rely on control of exposure through engineering and/or institutional controls to provide protection generally will be appropriate.” 55 Fed. Reg. 8700-01.

To summarize, the risk-based PRGs derived from the baseline risk assessments do not define protectiveness. Rather, protectiveness is part of the risk management step and is determined based on a number of factors including:

- ☐ Remediation goals that are conservative but realistic, *e.g.* based on exposures that can be reasonably expected to occur, but do not focus on worst-case exposure assumptions;
- ☐ The balancing of the NCP criteria;
- ☐ Factors related to uncertainty; and

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- That various methods may be used to achieve the risk levels including engineering and institutional controls.

Thus, it would be inaccurate to state that the comprehensive alternatives evaluated in the draft FS are not protective because they do not meet all the risk-based PRGs derived from the baseline risk assessments, including those that are below background concentrations. As documented in the draft FS, all of the comprehensive alternatives are protective of human health and the environment as defined by the NCP and EPA guidance documents.

3. ASSESSMENT OF PROTECTIVENESS IN THE DRAFT FS

Consistent with NCP and guidance, the draft FS established proposed ranges of Remedial Goals (RGs) that included EPA-directed PRGs and background levels, as well as additional RGs that are based on conservative but realistic exposure assumptions. These ranges of RGs achieve the target risk levels for the scenarios evaluated in the baseline risk assessments. (See Section 3.6 of the draft FS). Each alternative is evaluated for its potential to achieve levels within these RG ranges using the balancing of criteria under the NCP, particularly long-term and short-term effectiveness. These evaluations consider the uncertainties in projections of the long-term outcomes of the alternatives as well as uncertainties in the calculation of the RG ranges. Further, these evaluations also consider the engineering and institutional controls (e.g., fish advisories) that are part of all of the alternatives (except “no action”) to make a final determination whether each alternative meets the threshold criterion of protectiveness.

Alternatives B through F are projected to achieve similar sediment contaminant concentrations that are well within the RG ranges applied on an individual exposure scale and within the range of calculated upstream background concentrations. The alternatives also result in similar fish and shellfish tissue concentrations that are within the target tissue concentration ranges. As a result, Alternatives B through F were determined to be protective because they reasonably balance long- and short-term effectiveness, and include consideration of engineering and institutional controls.² (See Section 8 of the draft FS.) Notwithstanding, alternatives with smaller active remediation areas, volumes, and durations (e.g. Alternatives B and C) provide a much better balance of long- and short-term effectiveness.

² Two fish advisories exist for Portland Harbor. The fish advisory specific to Portland Harbor (Oregon Health Authority, 2004 and 2006) is for PCBs in resident fish and limits meals for healthy adults to one meal per month (assuming whole, unprepared fish) and advises children and pregnant or nursing women not to consume any resident fish. There is also an advisory (Oregon Health Authority, 2001) for the entire mainstem of the Willamette River for mercury. This advisory advises that women of child bearing age limit consumption of resident fish to one 8 oz meal per month, and healthy adults limit consumption of resident fish to one 8 oz meal per week. <http://public.health.oregon.gov/healthyenvironments/recreation/pages/1120esc.aspx>. The Portland Harbor remediation will not address the health risks due to mercury in fish and this advisory will remain in place after cleanup.

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4. CONCLUSION

The evaluation of protectiveness in the draft FS is consistent with the NCP and relevant guidance documents. The risk-based PRGs derived from the baseline risk assessments do not define protectiveness. Rather, the protectiveness of cleanup alternatives is part of risk management and is determined based on a number of factors as documented in the draft FS. All of the comprehensive alternatives are protective of human health and the environment as defined by the NCP and EPA guidance documents.

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ATTACHMENT A: EPA POLICY AND GUIDANCE

There are a number of CERCLA policy and guidance documents that provide further details on how risk characterization is conducted and how the protectiveness criterion should be evaluated in feasibility studies. Consistent themes throughout these documents are that the exposure assessment should be conservative but realistic and that the protectiveness determination should be based on several factors, including background concentrations.

(a) *Preamble to Final NCP*

Section 300.430. Remedial Investigation/Feasibility Study and Selection of Remedy (55 Federal Register 8701)

"The expectations also acknowledge that certain technological, economic and implementation factors may make treatment impracticable for certain types of site problems. Experience has shown that in such situations, remedies that rely on control of exposure through engineering and/or institutional controls to provide protection generally will be appropriate."

Section 300.430(d). Remedial investigation—baseline risk assessment. (55 Federal Register 8710-14).

The Preamble to the Final NCP includes a description of the objectives of the baseline risk assessment and how that relates to setting remedial goals:

"EPA conducts an exposure assessment to identify the magnitude of actual or potential human or environmental exposures, the frequency and duration of these exposures, and the routes by which receptors are exposed. This exposure assessment includes an evaluation of the likelihood of such exposures occurring and provides the basis for the development of acceptable exposure levels."

** * **

"EPA is clarifying its policy of making exposure assumptions that result in an overall exposure estimate that is conservative but within a realistic range of exposure. Under this policy, EPA defines "reasonable maximum" such that only potential exposures that are likely to occur will be included in the assessment of exposures. The Superfund program has always designed its remedies to be protective of all individuals and environmental receptors that may be exposed at a site; consequently, EPA believes it is important to include all reasonably expected exposures in its risk assessments. However, EPA does agree with a commenter that recommended against the use of unrealistic exposure scenarios and assumptions. The reasonable maximum exposure scenario is "reasonable"

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because it is a product of factors, such as concentration and exposure frequency and duration, that are an appropriate mix of values that reflect averages and 95th percentile distributions” (see the "Risk Assessment Guidance for Superfund: Human Health Evaluation Manual") (emphasis added).

“EPA does agree with one commenter that the likelihood of the exposure actually occurring should be considered when deciding the appropriate level of remediation, to the degree that this likelihood can be determined. The risk assessment guidance reference above is designed to focus the assessment on more realistic exposures. EPA has adopted these positions as policy and has not revised the regulation. In addition, EPA agrees that risk assessments conducted for Superfund should take into consideration background concentrations and conditions and should identify these critical assumptions and uncertainties in its risk assessments.”

* * *

“The results of the baseline risk assessment are used to understand the types of exposures and risks that may result from Superfund sites. Key assumptions and uncertainties in both contaminant toxicity and human and environmental exposure estimates must be documented in the baseline risk assessment, as well as the sources and effects of uncertainties and assumptions on the risk assessment results. Exposure assumptions or other information, such as additional toxicity information, may be evaluated to determine whether the risks are likely to have been under- or overestimated. These key assumptions and uncertainties must also be considered in developing remediation goals.”

* * *

“Information to develop final remediation goals is developed as part of the RI/FS process. Consequently, the use of preliminary remediation goals does not preclude the development and consideration or selection of alternatives that attain other risk levels. Final selection of the appropriate level of risk is made based on the balancing of criteria in the remedy selection step of the process.”

* * *

“To that end EPA developed the concept of reasonable maximum exposure, which is designed to include all exposures that can be reasonably expected to occur, but does not focus on worst-case exposure assumptions” (emphasis added).

* * *

“The risk assessment is one factor in the determination of what is protective.”

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Section 300.430(e)(9). Detailed analysis of alternatives. (55 Federal Register 8720)

“Long term effectiveness includes a consideration of the residual risk remaining at a site after the remedial action is complete. This assessment of risk is conducted assuming conservative but realistic exposures.”

(b) Guidelines for Carcinogen Risk Assessment. EPA/630/P-03/001F. March 2005.

EPA’s guidance documents advise against using overly conservative assumptions when identifying risks at a site:

“The intent of this approach is to convey an estimate of risk in the upper range of the distribution, but to avoid estimates that are beyond the true distribution. Overly conservative assumptions, when combined, can lead to unrealistic estimates of risk. This means that when constructing estimates from a series of factors (e.g., emissions, exposure, and unit risk estimates) not all factors should be set to values that maximize exposure, dose, or effect, since this will almost always lead to an estimate that is above the 99th percentile confidence level and may be of limited use to decisionmakers.” (Page 5-2).

Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA.

EPA/540/G-89/004OSWER Directive 9355.3-01. October 1988.

The identification of risk and assessment of the protectiveness of alternatives is discussed in EPA’s RI/FS guidance:

6.2.3.1 Overall Protection of Human Health and the Environment

“This evaluation criterion provides a final check to assess whether each alternative provides adequate protection of human health and the environment. The overall assessment of protection draws on the assessments conducted under other evaluation criteria, especially long-term effectiveness and permanence, short-term effectiveness, and compliance with ARARs.

Evaluation of the overall protectiveness of an alternative during the RI/FS should focus on whether a specific alternative achieves adequate protection and should describe how site risks posed through each pathway being addressed by the FS are eliminated, reduced, or controlled through treatment, engineering, or institutional controls. This evaluation also allows for consideration of whether an alternative poses any unacceptable short-term or cross-media impacts.”

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This 1988 guidance document is generally considered the definitive reference for conducting an RI/FS. As noted above, this guidance document clearly states that assessing the protectiveness of alternatives draws from other criteria, including long- and short-term effectiveness. It goes on to state that risks should be eliminated, reduced, or controlled through treatment, engineering, and/or institutional controls.

(c) *Role of Background in the CERCLA Cleanup Program.* OSWER 9285.6-07P. April 26, 2002.

The following guidance document explains how background should be assessed in risk assessments during risk characterization. It also includes a write-up on how important it is to articulate these differences to the community (*i.e.*, risk communication):

"In general, the presence of high background concentrations of hazardous substances, pollutants, and contaminants found at a site is a factor that should be considered in risk assessment and risk management" (emphasis added) (page 3).

* * *

"This policy encourages national consistency and responds to the Agency's goals for risk characterization and communication of risks to the public as expressed in other EPA policy and guidance, including:

- Policy for Risk Characterization which provides principles for fully, openly, and clearly characterizing risks"* (EPA, 1995b); and,
- Cumulative Risk Assessment Guidance which encourages programs to better advise citizens about the environmental and public health risks they face"* (EPA, 1997c) (pages 4-5).

"Definition of Terms:

Background refers to constituents or locations that are not influenced by the releases from a site, and is usually described as naturally occurring or anthropogenic" (EPA, 1989; EPA, 1995a):

"1) Anthropogenic – natural and human-made substances present in the environment as a result of human activities (not specifically related to the CERCLA release in question); and,

2) Naturally occurring – substances present in the environment in forms that have not been influenced by human activity" (page 5).

* * *

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“Guidance for determining if site risks are unacceptable is discussed in the EPA (1991) Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions. As stated in the EPA (1991) memorandum, EPA uses the general 10^{-4} to 10^{-6} risk range as a “target range” within which the Agency strives to manage risks as part of a Superfund cleanup. The risk used in this decision generally is the “cumulative site risk” to an individual using reasonable maximum exposure (RME) assumptions for either current or future land use and includes all exposure pathways which the same person may consistently face.” See also EPA (1989) RAGS, Section 8.3. (Footnote 3 on page 6.)

* * *

“In RAGS, EPA cautioned that eliminating COPCs based on background (either because concentrations are below background levels or attributable to background sources) could result in the loss of important risk information for those potentially exposed, even though cleanup may or may not eliminate a source of risks caused by background levels. In light of more recent guidance for risk-based screening (EPA, 1996; EPA, 2000) and risk characterization (EPA, 1995c), this policy recommends a baseline risk assessment approach that retains constituents that exceed risk-based screening concentrations. This approach involves addressing site-specific background issues at the end of the risk assessment, in the risk characterization, and if data are available, the contribution of background to site concentrations should be distinguished” (emphasis added) (page 6).

* * *

“The contribution of background concentrations to risks associated with CERCLA releases may be important for refining specific cleanup levels for COCs that warrant remedial action.⁶ Generally, under CERCLA, cleanup levels are not set at concentrations below natural background levels. Similarly, for anthropogenic contaminant concentrations, the CERCLA program normally does not set cleanup levels below anthropogenic background concentrations” (page 7).

⁶*For example, in cases where a risk-based cleanup goal for a COC is below background concentrations, the cleanup level may be established based on background.”.*

* * *

“EPA strives for transparency in decision-making (EPA, 1995c) and encourages programs to better advise citizens about the environmental and public health risks they face (EPA, 1997c). The presence of high background concentrations of COPCs may pose challenges for risk communication. For example, the discussion of

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background may raise the expectation that EPA will address those risks under CERCLA. The knowledge that background substances may pose health or environmental risks could compound public concerns in some situations.

On the other hand, knowledge of background risks could help some community members place CERCLA risks in perspective. Also, the information about site and background risks can be helpful for both risk managers who make an appropriate CERCLA decision, and for members of the public who should know about environmental risk factors that come to light during the remedial investigation process" (page 8).

The concepts of risk characterization, background, protectiveness, and institutional controls presented in the above-listed reference documents are also supported in the following:

EPA. 2002b. Principles for Managing Contaminated Sediment Risks at Hazardous Waste Sites. U.S. Environmental Protection Agency, Office of Emergency and Remedial Response, Washington, DC. OSWER Directive 9285.6-08. February.

EPA. 2005a. Contaminated Sediment Remediation Guidance for Hazardous Waste Sites. OSWER Publication 9355.0-85 DRAFT. United States Environmental Protection Agency, Office of Solid Waste and Emergency Response. Website: <http://www.epa.gov/superfund/resources/sediment/guidance.htm>. Washington, D.C.

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